REMARKS/ARGUMENTS

This is a preliminary amendment in a RCE application. Applicants withdraw the subject application from appeal and request that prosecution be reopened. The Office Action mailed March 9, 2009 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims originally in the application were claims 1-35. Claims 2, 3, 7, 8, 9, 10, 22, 23, 24, 26, 27, 28, 29, 30, and 33 have been cancelled. The claims presented for examination are: claims 1, 4-6 11-21, 25, 31, and 34-35.

Applicants' invention provides an apparatus and a method for closure of a physical anomaly that forms a gap in a vascular wall. Applicants' invention provides a closure body made of a shape memory polymer (SMP) foam. The shape memory polymer (SMP) foam has at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at a temperature below T_{trans}. Applicants' invention is illustrated in FIGS. 1, 2, 3, and 5B reproduced below and described in the portions of the specification quoted below.

> The present invention provides apparatus and methods for closure of a physical anomaly. The closure is provided by a polymer body with an exterior surface. The exterior surface contacts the opening of the anomaly and closes the anomaly. The polymer body has a primary shape for closing the anomaly and a secondary shape that allows it to be positioned in the physical anomaly. (Page 7, Lines 22-26 of Applicants' Specification)

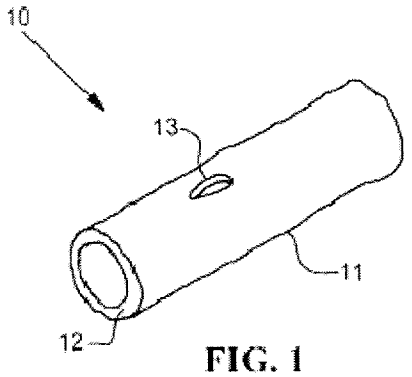


FIG. 1

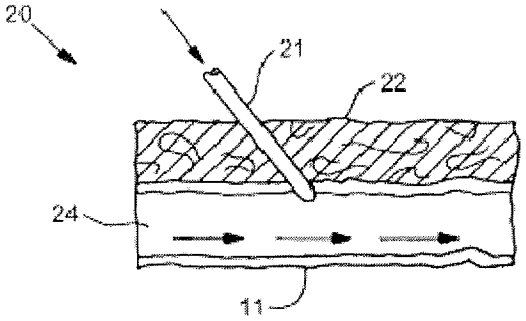


FIG. 2

FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, Lines 20-21 of Applicants' Specification) In order to close such sites,

a closure body, in one embodiment a polymeric foam, is advanced to the puncture site in order to seal the site. (Page 9, Lines 5-6 of Applicants' Specification)

FIG. 3

FIG. 3 is a schematic of a closure body 31 in its expanded state and the closure body 31' in its compressed state. The closure body 31' is compressed to a smaller volume before deployment. (Page 10, Lines 15-17 of Applicants' Specification)

SMP foams comprise at least one hard segment and one soft segment. One segment contains a crosslinkable group; linking occurs via charge transfer, chemical or physical segment interactions. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment can return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, Lines 11-16 of Applicants' Specification)

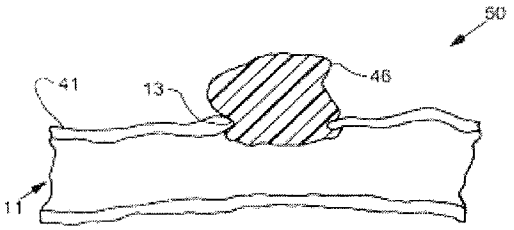


FIG. 5B

Full deployment of the SMP foam closure device is shown in FIG. 5B. The closure body 46 is shown in its expanded state (as opposed to compressed state) to fill the gap in the vessel wall in its entirety. In FIG. 5B, the puncture tract 45 is shown with the delivery catheter removed and with the closure body 46 in its expanded (actuated) state. (Page 13, Lines 24-26 of Applicants' Specification)

35 U.S.C. § 103(a) Rejection - Evans in view of Bleys

Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans et al U. S. Patent No. 5,549,633 (hereinafter "Evans") in view of Bleys et al U. S. Patent No. 6,034,149 (hereinafter" Bleys"). The rejection is stated in numbered paragraph 3 on pages 3-4 of the March 9, 2009 Office Action.

Legal Standard

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

Inquiry (A) - Determining the scope and content of the prior art; and

Inquiry (B) - Ascertaining the differences between the claimed invention and the prior art; and

Inquiry (C) - Resolving the level of ordinary skill in the pertinent art.

Inquiry (A) - Scope and Content of the Prior Art

The Evans Reference

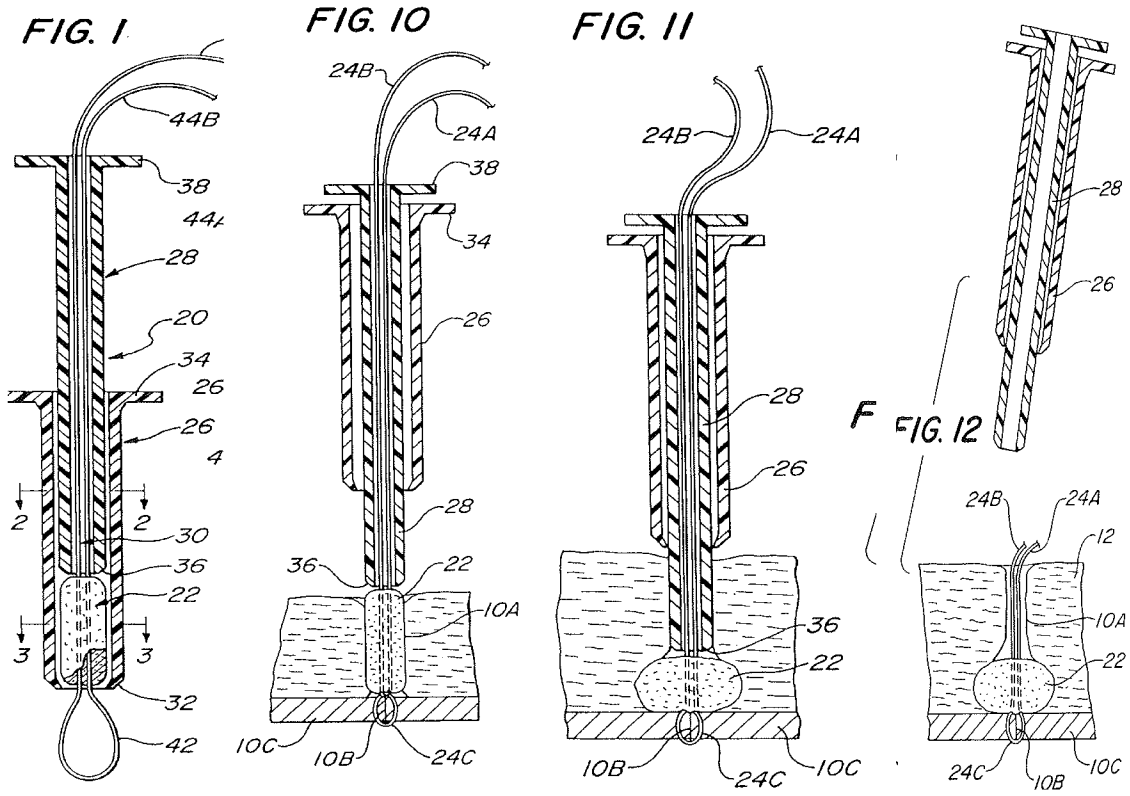
The Evans reference (U.S. Patent No. 5,549,633) is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). This is substantially different from Applicants' claimed invention which is a "closure of a physical anomaly that forms a gap in a vascular wall." A percutaneous puncture site (puncture tract) is in the tissue outside a vascular wall and is not in the vascular wall itself. Applicants' claimed invention closes a physical anomaly that forms a gap in a vascular wall." The Evans reference is a device for preventing blood seepage in the puncture tract tissue outside the vascular wall. The Evans reference is illustrated in FIGS. 1, 10, 11, and 12 reproduced below and described in the portions of the Evans reference quoted below.

> "Perclose, Inc. of Menlo Park, Calif. has recently disclosed a percutaneous vascular closure device which it designates by the trademark PROSTAR. The PROSTAR device is arranged to be inserted through a percutaneous puncture into a artery to seal the opening in the arterial wall. To that end the PROSTAR device inserts plural needles having sutures secured thereto through the percutaneous puncture and into the interior of the artery. The needles are then drawn from the interior of the artery through the arterial wall portion surrounding the puncture and out through the puncture tract, where they are grasped to pull the associated sutures out of the puncture tract. The extending portions of the sutures are knotted within the puncture tract and the knots are pushed into the tract by an associated device, designated as the PROSTAR knot pusher, so that the knots are closely adjacent or abutting the exterior of the artery wall. This action ostensibly seals the opening in the artery wall. It is believed that there may be some blood seepage out of the puncture tract when using the PROSTAR system."

> "Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 one embodiment of apparatus constructed in accordance with this invention. The apparatus 20 is arranged to be used to apply a self-supporting mass or body of material 22, e.g., collagen like that disclosed in the aforementioned patent, to inhibit the flow of the fluid, e.g., blood, therethrough at or immediately adjacent a percutaneous

puncture 10 (FIG. 7) which had been sealed or closed by some means located within the tract of the puncture to prevent the seepage of fluid from the puncture. In the embodiment shown in FIGS. 7-12 the apparatus 20 is shown applying that mass of material 22 into an arterial puncture tract 10A extending through the skin and underlying tissue 12 so that the mass 22 is adjacent the hole or opening 10B in the wall 10C of the artery."

"As will be appreciated from the discussion to follow the apparatus 20 is arranged to place the mass or body 22 either into the percutaneous puncture tract 10A or on the surface of the skin 12 above and contiguous with the puncture 10 to enable the mass to be secured in place in close engagement with the tissue of the puncture tract so that it reduces or prevents the seepage of a fluid from the puncture 10."



"As can be seen in FIG. 1 the apparatus or device 20 basically comprises a tubular housing 26, a tamping member 28, the heretofore identified mass or body 22 of material which is resistant to the passage of a fluid therethrough, and a flexible carrier filament 30. In accordance with a preferred embodiment of this invention the mass or body 22 is composed of collagen foam, since that material enables blood to readily clot therein, thus expediting hemostasis (blood flow stoppage) when the application is used to prevent the seepage of blood from a percutaneous puncture to a blood vessel or some other interior structure in the body of the being. In particular, the mass is preferably a porous sponge of Type 1 collagen marketed by Collatec, Inc. under the trade name HELISTAT. This material is a natural hemostatic material to provide hemostasis and the elimination of any "weeping" or seeping of blood due to incomplete closure of the puncture site by the sutures, as will be described later. Other hemostatic materials, such as cellulose-based, hemostatic materials manufactured and sold by Upjohn Company under the trademark GELFOAM, can also be used for the mass 22. Other blood clotting materials can be used in lieu of collagen. In fact the material of the mass 22 need not even absorb the blood nor promote blood clotting therein, so long as it is resistant to the passage of a fluid therethrough."

"The tubular housing 26 basically comprises a hollow cylinder having an open, slightly inwardly tapered, distal free end 32 and an outwardly flanged proximal free end 34. The housing 26 is arranged to retain the mass 22 therein until it is to be deployed, i.e., expelled or ejected, from the device for disposition at the puncture tract (as will be described later). To that end the housing is shaped so that it can be readily held in the hand of the user to locate it at the desired position for deploying the mass 22. The deployment of the mass from the apparatus is effected by retraction of the housing 26 with respect to the tamper 28 as will be described later."

"The tamper 28 basically comprises a hollow tube having an open distal free end 36 and a flanged proximal free end 38. The outside diameter of the tamper is slightly less than the inside diameter of the housing 26 so that it fits therein and is slidable longitudinally with respect thereto. This enables the housing 34 to be slid or retracted backward with respect to the plunger to expel or eject the mass 22 from the housing. Once the mass 22 has been expelled from the housing the tamper 28 is used to tamp it in place into intimate engagement with tissue contiguous with the puncture tract 10A, i.e., tissue within the tract or the surface of the skin contiguous with the tract, as will be described later."

"The carrier filament 30 basically comprises an elongated flexible member, e.g., a conventional suture, which is folded in two to form a looped distal end 42 and a pair of extending leg portions 44A and 44B. The flexible member 30 extends through the central passageway 40 in the mass 22 so that its looped distal end 42 extends outside (i.e., distally) of the housing's open end 32, and with its leg portions 44A and 44B extending through the hollow interior of the tamper 28 gaining egress out the proximal flared end 38 thereof."

"The apparatus 20 is now ready to deploy the mass 22. To that end the user orients the apparatus so that the distal end 32 of the housing 26 is extended into the puncture tract 10A, like shown in FIG. 9. In this position the mass 22 is disposed immediately over the knot 24D. During the insertion of the distal end of the apparatus into the puncture tract the proximal portions 44A and 44B of the suture are pulled to make them somewhat taut. This facilitates the insertion procedure. Once the apparatus 20 is in position, the housing 26 is slid backward (retracted) with respect to the tamper 28 by squeezing their two flanged portions 34 and 38, respectively together, while holding the tamper 38 stationary. This action ejects the mass 22 into the puncture tract 10A, whereupon the mass is disposed immediately over the arterial wall, like shown in FIG. 10."

"In order to seat the mass the tamper 28 and housing 26 are then moved as a unit so that the distal end 36 of the tamper 28 engages the mass 22 to deform it as shown in FIG. 11. One or two gentle tamping actions are all that should be necessary to ensure that the mass 22 is in intimate engagement with the sutured opening 10B in the arterial wall. The housing and tamper is then withdrawn as a unit from the puncture tract 10A, as shown in FIG. 12, leaving the mass 22 in place."

"It should be pointed out at this juncture that the frictional engagement between the inner surface of the passageway 40 of the mass 22 and the exterior surface of the extending portions 24A and 24B of the suture 24 should be sufficient to hold the mass 22 in place in the puncture tract 10A to reduce or prevent any blood from seeping out of the puncture tract. Since the mass 22 is preferably formed of a material which promotes clotting upon receipt of blood therein, hemostasis should occur rapidly, thereby quickly preventing any further seepage of blood from the puncture tract."

The Bleys Reference

The Bleys reference is U.S. Patent No. 6,034,149 showing hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. In general such absorbent articles are

relatively voluminous; in particular diapers occupy a lot of space in shops and stores. It would be an advantage to reduce the volume of such absorbent articles without imparting the other properties."

Inquiry (B) - Differences Between Claimed Invention and the Prior Art

With regard to factual inquiry (B) Ascertaining the differences between the claimed invention and the prior art, Applicant points out that Applicants' invention is very different from the apparatus and methods disclosed in the Evans and Bleys references.

The Evans reference percutaneous puncture site is located in the tissue outside the vascular wall and is not in the vascular wall itself as in Applicants' invention and claimed in Applicants' claims on appeal. The Evans reference states: "apparatus 20 is arranged to place the mass or body 22 either into the percutaneous puncture tract 10A or on the surface of the skin 12 above and contiguous with the puncture 10." (Col. 6, lines 9-11 of the Evans Reference) By contrast, Applicants' claimed invention is an apparatus for closure of a physical anomaly that forms a gap in a vascular wall. Differences between Applicants' claimed invention and the Evans reference are illustrated by the side by side comparison of FIG. 5B from Applicants' application and FIG. 10 from the Evans reference provided below.

Evans Reference

FIG. 10

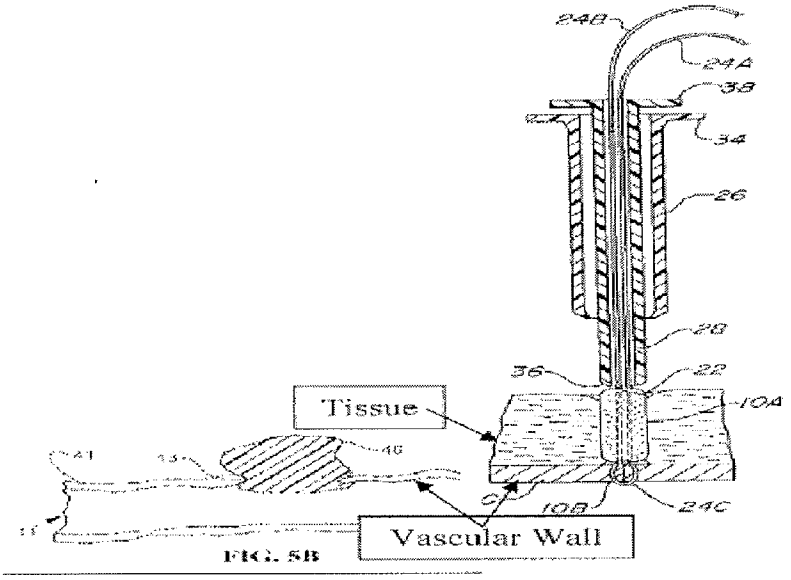


FIG. 5B

Appellants' Invention

Applicants' claimed invention is an apparatus for closure of a physical anomaly that forms a gap in a vascular wall. Applicants' claims include the claim limitations "deploy said closure body into the physical anomaly in the vascular wall" and "said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall" and "recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly." The Evans reference apparatus 20 is arranged to place the mass or body 22 into the percutaneous puncture tract 10A in the tissue or on the surface of the skin 12 in the tissue above the percutaneous puncture 10."

Applicants' invention is very different from the apparatus and methods disclosed in the Evans and Bleys references and example of Applicants' claim elements that are not shown by either the Evans reference or the Bleys reference are identified and described below.

Claim 1
"An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Claim 5
"The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

Claim 25
"The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further

comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

Claim 32

"A system for the closure of a physical anomaly that forms a gap in a vascular wall," or

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," or

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" or

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Inquiry (C) - Level of Ordinary Skill in the Pertinent Art

With regard to factual inquiry (C) Resolving the level of ordinary skill in the pertinent art, Applicant points out that individuals working in the art are generally, engineers or scientists working in research or development.

Procedural Standards

The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.

Criterion 1 - The prior art reference (or reference when combined) must teach or suggest all the claim limitations.

Criterion 2 - There must be a reasonable expectation of success with the proposed combination.

Criterion 3 - The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Criterion 1 - References Do Not Teach All Claim Limitations

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. With reference to the descriptions of the Evans and Bleys references above, it is clear that the references fail to teach the following limitations of Applicants' claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35:

Claim 1

"An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Claim 5

"The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

Claim 25

"The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

Claim 32

"A system for the closure of a physical anomaly that forms a gap in a vascular wall," or

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," or

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" or

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Thus, the combination of the Evans and Bleys references in the Office Action mailed March 9, 2009 does not teach all of Applicants' claim limitations and the combination of the Evans and Bleys references fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be withdrawn.

Criterion 2 - No Reasonable Expectation of Success

The criterion that there must be a reasonable expectation of success with the proposed combination has not been met. There could be no combination of the Evans reference and the Bleys reference that would provide a reasonable expectation of success or that would show Applicants' invention of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35.

Both the Evans reference and the Bleys reference fail to disclose Applicants' claim 1 limitations: "An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature

below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Both the Evans reference and the Bleys reference fail to disclose Applicants' claim 5 limitations: "The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

Both the Evans reference and the Bleys reference fail to disclose Applicants' claim 25 limitations: "The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger."

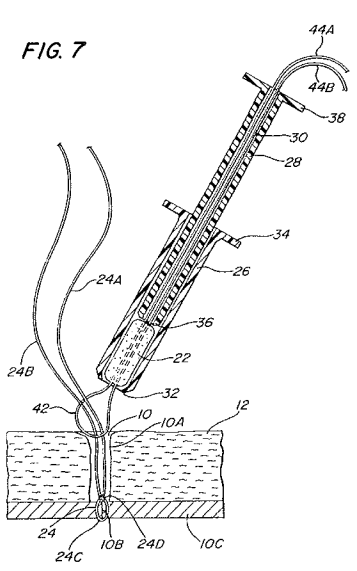
Both the Evans reference and the Bleys reference fail to disclose Applicants' claim 32 limitations: "A system for the closure of a physical anomaly that forms a gap in a vascular wall," "a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "a delivery device adapted to received said closure body made

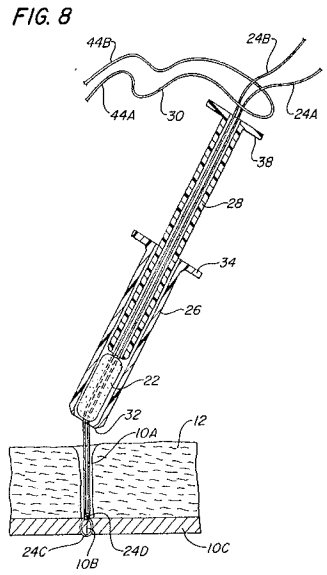
of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," "said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," "means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Since these elements are missing from both references there could be no combination of the two references that would have reasonable expectation of success of providing Applicant's invention of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35.

The Evans reference requires a carrier filament 30 that basically comprises an elongated flexible member, e.g., a conventional suture, which is folded in two to form a looped distal end 42 and a pair of extending leg portions 44A and 44B. The loop 42 of the carrier filament 30 is adjacent the puncture tract whereupon the extending portions 24A and 24B of the closure 24 are extended or passed through the interior of the loop. Once the extending portions 24A and 24B of the suture are passed through the carrier filament loop 42, the proximally extending portions 44A and 44B of carrier filament are pulled in the proximal direction. This action pulls the extending suture portions 24B and 24C through the passageway 40 of the mass 22, and through the interior of the tamper 28 until those extending portions are located proximally of the flanged end 38. The Bleys reference device does not work with a carrier filament 30 of the Evans reference.

The Evans reference apparatus and method requires that the loop 42 of the carrier filament 30 be anchored to the opening in the artery to pull the mass 22 into the percutaneous puncture tract 10A above the artery. This is illustrated in FIGS. 7 and 8 of the Evans reference reproduced below and described in Col. 7, lines 45-57 of the Evans reference reproduced below.





The apparatus 20 is held by the user so that the loop 42 of the carrier filament 30 is adjacent the puncture tract like shown in FIG. 7, whereupon the extending portions 24A and 24B of the closure 24 are extended or passed through the interior of the loop by any suitable means (not shown). Once the extending portions 24A and 24B of the suture are passed through the carrier filament loop 42, the proximally extending portions 44A and 44B of carrier filament are pulled in the proximal direction. This action pulls the extending suture portions 24B and 24C through the passageway 40 of the mass 22, and through the interior of the tamper 28 until those extending portions are located proximally of the flanged end 38, as shown in FIG. 8.

It would be impossible to place the mass 22 of the Evans reference in the opening in the artery because there is no place to anchor the loop 42 of the carrier filament 30 to pull the mass 22 into the opening in the artery. This is better understood with reference to FIG. 2 of Appellants' application reproduced below.

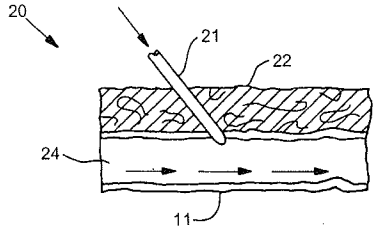


FIG. 2

As shown by FIG. 2 of Appellants' application above, there is no place to anchor a loop of a carrier filament to pull a mass into the opening in the artery as required by the Evans reference.

Thus, the combination of the Evans and Bleys references in the Office Action mailed March 9, 2009 fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-

21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be withdrawn.

Criterion 3 – No Reasons for Combining the References

The criterion that the Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007" has not been met. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination. There could be no combination of the Evans reference and the Bleys reference that would show Applicant's invention of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35.

The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Bleys reference shows hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. There are no reasons for combining these two dissimilar systems. Further, a combination of the Evans reference and the Bleys reference would not show Applicant's invention of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35.

Thus, the combination of the Evans and Bleys references in Grounds of Rejection #1 of the Office Action mailed March 9, 2009 fails to support a rejection of claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be withdrawn.

35 U.S.C. § 103(a) Rejection - Evans in view of Bleys & Duane

Claims 6, 13, and 15 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans in view of Bleys and further in view of Duane et at U. S. Patent No. 5,836,306 (hereinafter" Duane"). The rejection is stated in numbered paragraph 6 on page 5 of the March 9, 2009 Office Action.

Legal Standard

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

Inquiry (A) - Determining the scope and content of the prior art; and

Inquiry (B) - Ascertaining the differences between the claimed invention and the prior art; and

Inquiry (C) - Resolving the level of ordinary skill in the pertinent art.

Inquiry (A) - Scope and Content of the Prior Art

The Evans reference and the Bleys reference are described above.

The Duane Reference

The Duane reference (U.S. Patent No. 5,836,306) is an exchange accessory for use with a monorail catheter. The Duane reference is illustrated in FIG. 1 reproduced below and described in the portions of the Duane reference quoted below.

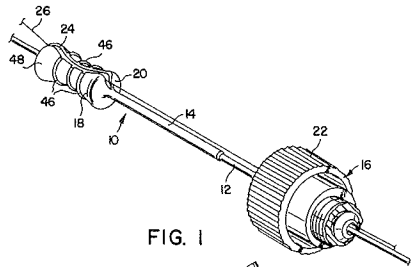


FIG. 1

"Referring now to FIG. 1, a preferred embodiment of the exchange accessory 10 is shown mounted on the proximal end of the shaft of a monorail catheter 12. The exchange accessory 10 includes a sleeve portion 14 that is adapted to be received in a connector 16 (shown broken away). The connector is conventionally mounted on the proximal end of a guide catheter (not shown) , external to the patient. The connector 16 may be, for example, a Tuohy-Borst connector or any suitable connector which permits axial positioning of the catheter 12 and permits introduction of a contrast medium or medicament through the guide catheter and into the patient's vascular system. In accordance with one aspect of the invention, the sleeve portion 14 has an internal diameter which is greater than and complementary with the external diameter of the shaft of the particular catheter 12. Thus, the sleeve portion 14 defines a space about the shaft of the catheter 12 sufficient to allow backbleed of blood therethrough in a controlled manner. To facilitate discussion, the shaft of the catheter 12 is more generally referred to as the catheter 12."

Inquiry (B) - Differences Between Claimed Invention and the Prior Art

With regard to factual inquiry (B) Ascertaining the differences between the claimed invention and the prior art, Applicant points out that the Evans, Bleys, and Duane references fail to teach the following limitations of Appellants' claims 6, 13, and 15:

Claim 6

"The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Claim 13
"The apparatus of claim 1 wherein said delivery device includes a backbleed tube."

Claim 15
"The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube."

Inquiry (C) - Level of Ordinary Skill in the Pertinent Art

With regard to factual inquiry (C) Resolving the level of ordinary skill in the pertinent art, Applicant points out that individuals working in the art are generally, engineers or scientists working in research or development.

Procedural Standards

The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.

Criterion 1 - The prior art reference (or reference when combined) must teach or suggest all the claim limitations.

Criterion 2 - There must be a reasonable expectation of success with the proposed combination.

Criterion 3 - The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Criterion 1 - References Do Not Teach All Claim Limitations

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations has not been met. With reference to the descriptions of the Evans, Bleys, and Duane references above, it is clear that the references fail to teach the following limitations of Appellants' claims 6, 13, and 15:

Parent Claim 1
"An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Claim 6
"The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Thus, the combination of Evans, Bleys, and Duane references in the Office Action mailed March 9, 2009 does not teach all of Appellants' claim limitations and the combination of Evans, Bleys, and Duane references fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a), and the rejection should be withdrawn.

Criterion 2 - No Reasonable Expectation of Success

The criterion that there must be a reasonable expectation of success with the proposed combination has not been met. There could be no combination of Evans, Bleys, and Duane references that would provide a reasonable expectation of success or that would show Appellants' invention of claims 6, 13, and 15.

The Evans, Bleys, and Duane references fail to disclose Appellants' parent claim 1 limitations: "An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," "wherein

said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

The Evans, Bleys, and Duane references fail to disclose Appellants' claim 6 limitations: "The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Since these elements are missing from all three references there could be no combination of the three references that would have reasonable expectation of success of providing Appellant's invention of claims 6, 13, and 15.

Thus, the combination of Evans, Bleys, and Duane references in the Office Action mailed March 9, 2009 fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a), and the rejection should be withdrawn.

Criterion 3 – No Reasons for Combining the References

The criterion that the Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007" has not been met. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination. There could be no combination of Evans, Bleys, and Duane references that would show Appellant's invention of claims 6, 13, and 15.

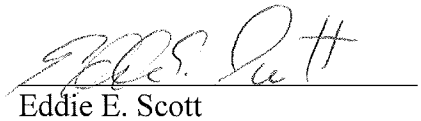
The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Bleys reference shows hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. The Duane reference is an exchange accessory for use with a monorail catheter. There are no reasons for combining these three dissimilar systems. Further, a combination of the Evans, Bleys, and Duane references would not show Appellant's invention of claims 6, 13, and 15.

Thus, the combination of Evans, Bleys, and Duane references in Grounds of Rejection #2 of the Office Action mailed March 9, 2009 fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a), and the rejection should be withdrawn.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated March 9, 2009 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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Dated: 1/14/2011